

REMARKS

Objection to the Specification under 35 U.S.C. § 132(a)

In the final Office Action, dated 05/10/2006, the Examiner has objected to amended paragraph [0065] asserting that new matter has been introduced by the prior amendment.

In the prior response, dated 07/10/2006, Applicant has amended paragraph [0065] to delete the subject matter identified by the Examiner.

Accordingly, the objection to the specification is now moot.

Rejection under 35 U.S.C. § 112, first paragraph

Claims 24 and 28 are rejected under 35 U.S.C. § 112, first paragraph as failing to comply with the enablement requirement.

Specifically, the Examiner states that “the specification...would not convey to one having ordinary skill in the art that the repetition parameter defines a number of pulses to be generated for a set of stimulation pulses within a cycle independent from one or several pulse frequency parameters.” Likewise, the Examiner identifies the limitation generating adjacent pulses according to a frequency parameters as being non-enabled.

In regard to the limitation “repetition parameter defines a number of pulses to be generated for a set of stimulation pulses within a cycle independent from one or several pulse frequency parameters,” Applicant respectfully disagrees with the Examiner’s position. However, solely for the purpose of expediting prosecution, Applicant has cancelled the limitation from the claims.

In regard to generating adjacent pulses according to a frequency parameter, Applicant respectfully submits that limitation satisfies all requirements under 35 U.S.C. § 112, first paragraph.

The question of enablement under 35 U.S.C. § 112, second paragraph is whether one of ordinary skill in the art would be capable of making and using the claimed subject matter. The Examiner bears the burden of establishing a prima facie case of non-enablement.

Specifically, the Patent Office bears an initial burden of setting forth a reasonable explanation why it believes that the scope of protection provided by the claim is not adequately enabled by the description of the invention provided in the specification of the application. *In re Oetiker*, 24 USPQ 2d 1443, 1444 (Fed. Cir. 1992). Additionally, as an initial burden for an enablement rejection, the Patent Office must show why the disclosure would require “undue experimentation” in making and using the claimed subject matter. *In re Angstadt*, 190 USPQ 214, 219 (CCPA 1976).

Applicant further notes that a patent application need not teach, and preferably omits, what is well known in the art. *In re Buchner*, 18 USPQ2d 1331, 1332 (Fed. Cir. 1991); *Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 231 USPQ 81, 94 (Fed. Cir. 1986), cert. denied, 480 U.S. 947 (1987).

Applicant submits that the rejection is deficient, because the Examiner has not considered and properly weighed the knowledge of “stimulation sets” that one of ordinary skill in the art would possess. As an example and without limitation, Applicant refers the Examiner to PCT publication number WO 01/93953 A1, entitled “Neuromodulation Therapy System,” published December 13, 2001 which has been made of record in a concurrently filed IDS. The PCT publication describes to one of ordinary skill in the art how to control the generation of stimulation pulses for multiple stimulation sets as controlled by one or several frequency parameters. Specifically, the PCT publication describes using a microprocessor to control the time that any one stimulation setting is executed. The microprocessor is described to define a period between stimulation pulses based on a frequency of the stimulation setting (e.g., two cycles, three cycles) as one example of the pulse timing control. *See* WO 01/93953 A1, page 11, lines 15-19.

Applicant further refers the Examiner to EP application number EP 0 811 395 A2, entitled “Multiprogrammable tissue stimulator,” published December 10, 1997, which has been made of record in a concurrently filed IDS. The EP application discloses circuitry that can be utilized to control the frequency between adjacent stimulation pulses, such as a clock, frequency divider, and a microprocessor. *See* col. 7, line 50 - col. 8, line 58 of EP 8 811 395 A2.

Furthermore, the present application describes clock-driven pulse generating circuitry that operates according to a frequency parameter (among other parameters). *See* application, paragraph [0048] and shows adjacent pulses within the stimulation set separated from each other in the manner as claimed. *See, e.g.,* FIGS. 6A-6C.

Accordingly, one of ordinary skill in the art would know how to make and use the claimed subject matter from the present application and from the knowledge of one of ordinary skill in the art.

Applicant respectfully requests the Examiner to withdraw the rejection under 35 U.S.C. § 112, first paragraph.

Rejection under 35 U.S.C. § 103(a)

Claims 24, 26-28, and 30-31 are rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent Application Publication No. 2001/0007950 by North et al. (hereinafter “North”) in view of U.S. 5,324,317 to Reiss (hereinafter “Reiss”).

Claims 25 and 29 are rejected under 35 U.S.C. § 103(a) as being unpatentable over North in view of U.S. Patent No. 5,038,781 to Lynch (hereinafter “Lynch”) in further view of Reiss.

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the applied reference (or references when combined) must teach or suggest all the claim limitations. *See* MPEP § 2143. Applicant respectfully submits that the applied references do not satisfy these criteria.

The North and Reiss Combination

Currently pending claims 24, 26-27, 28 and 30-31 are rejected in view of the combination of North and Reiss.

Claim 24 recites:

maintaining a plurality of stimulation sets of stimulation parameters with each set of stimulation parameters defining at least a pulse characteristic and an electrode configuration in memory of the neurostimulator;

maintaining a repetition parameter for at least one of the plurality of stimulation sets in memory of the neurostimulator, wherein the repetition parameter identifies a number of times that a pulse is to be repeated in a consecutive manner for the at least one stimulation set; and

stimulating living tissue(s) using a substantially continuous set of pulses wherein the stimulating includes (i) successively selecting a stimulation set from the plurality of stimulation sets in a cyclical manner; (ii) generating a pulse according to the pulse characteristic of the selected stimulation set; and (iii) delivering the generated pulse to living tissue(s) through electrodes according to the electrode configuration of the selected stimulation set;

wherein the stimulating repeats the generating and delivering for the at least one of the plurality of stimulation sets according to the repetition parameter in a consecutive manner.

Claim 28 recites:

memory storing a plurality of stimulation sets of stimulation parameters with each set of stimulation parameters defining at least a pulse characteristic and an electrode configuration;

the memory further storing a repetition parameter for at least one of the plurality of stimulation sets, wherein the repetition parameter identifies a number of times that a pulse is to be repeated in a consecutive manner for the at least one stimulation set; a pulse generator that outputs a pulse having a pulse characteristic; and a microprocessor operating under executable instructions that:

(i) successively selects a stimulation set from the plurality of stimulation sets in a cyclical manner;

(ii) loads the pulse characteristic into a pulse control associated with the pulse generator;

(iii) configures an output switch matrix according to the electrode configuration of the selected stimulation set;

(iv) causes the pulse generator to output at least one pulse after the loading and configuring, wherein the microprocessor causes the pulse generator to generate adjacent pulses according to a frequency parameter; and

(v) when the selected stimulation set is the at least one stimulation set associated with the repetition parameter, repeating (iv) according to the repetition parameter within a stimulation cycle.

North is merely directed to a “universal interface” for adjusting conventional stimulation parameters (e.g., amplitude, pulse width, and frequency) of a neurostimulator. See Abstract and paragraph [0009] of North. Accordingly, Applicant respectfully submits North does not teach or suggest a “repetition parameter” as specifically claimed.

In the Office Action, the rejection of these claims states that “Reiss teaches of an interferential stimulation that comprises a repetition parameter.” The rejection cites col. 1, lines 62-68 and col. 2, lines 1-16 of Reiss to support this proposition. *See* Office Action, page 2.

The portion of Reiss upon which the rejection relies is as follows:

The interferential stimulator includes a mode control to permit changing the sequence of stimulation to prevent accommodation to the unit and to enable a number of alternatives to be evaluated to find the most effective pain relief. In the first mode, the unit is operated in a continuous manner at one set of frequencies. In a second mode the stimulator operates at a set pulse rate for a short period, such as about one second, drops to a much lower pulse rate, such as about 50% for a short period, such as about one second, then repeats. In a third mode, the stimulator operates at a set pulse rate for a period of from about 1 to 15 seconds (preferably about 8 seconds), drops to a much lower rate, typically about 50%, for from about 1 to 15 seconds (preferably the same length as the first period), then repeats. In a fourth mode, the stimulator operates at a set pulse rate for a period of from about 1 to 15 seconds (preferably about 10 seconds) then slowly drops to a much lower pulse rate, typically about 50% of the set value over a period of from about 1 to 15 seconds (preferably the same as the initial operation period), then repeats. These periods, degree of decrease between sequences and the initial set pulse rate may be varied, where suitable, if desired.

Col. 1, lines 62-68 and col. 2, lines 1-16.

Reiss merely states that stimulation occurs at a predetermined pulse rate for a given period of time and then the pulse rate is lowered for another amount of time. The process is repeated by again starting with the high pulse rate and changing to the lower pulse rate. Reiss merely discloses repeatedly switching back and forth between a high rate of stimulation and a lower rate of stimulation.

Thus, there are two different types of parameters in the portion of Reiss cited in the Office Action. Specifically, Reiss discloses frequency or “rate parameters” for the first and second periods. Also, Reiss discloses “time parameters” (values from 1 to 15 seconds) defining the duration of the first and second periods of time.

Neither of the types of parameters of Reiss teaches or suggests the repetition parameter as specifically claimed. Specifically, the repetition parameter of claims 24 and 28 “identifies a number of times that a pulse is to be repeated in a consecutive manner for the at

least one stimulation set.” By utilizing such a repetition parameter, the claimed subject matter enables complex tissue stimulation patterns that are not taught or suggested by Reiss (or North).

Therefore, North and Reiss (either individually or in combination) do not teach or suggest each and every limitation of claims 24 and 28. A prima facie case of obviousness has not been established for these claims. Claims 26-27 and 30-31 respectively depend from claims 24 and 28 and, hence, a prima facie case of obviousness has not been established for claims 26-27 and 30-31.

The North, Reiss, and Lynch Combination

Currently pending claims 25 and 29 are rejected over the combination of North, Reiss, and Lynch. Claims 25 and 29 respectively depend from base claims 24 and 28 and, hence, inherit all limitations of their base claim.

For the reasons discussed above, the combination of North and Reiss fails to teach or suggest the “repetition parameter” as recited.

Lynch is merely directed to a functional electro-stimulation (FES) system that verifies stimulation parameters using parity codes. See col. 13, lines 30-44 of Lynch. Lynch does not teach or suggest a repetition parameter as claimed.

Thus, the applied references (either individually or in combination) do not teach or suggest each and every limitation of claims 25 and 29. A prima facie case of obviousness has not been established for claims 25 and 29.

New Claims

Applicant has added new claims 32-35. The new claims are supported by the original application. No new matter has been entered.

Claim 32 recites:

maintaining a plurality of stimulation sets of stimulation parameters with each set of stimulation parameters defining at least a pulse characteristic and an electrode configuration in memory of the neurostimulator;

maintaining a repetition parameter for at least one of the plurality of stimulation sets in memory of the neurostimulator, wherein the repetition parameter identifies a number of times that a pulse is to be repeated within a single cycle through the plurality of stimulation sets; and

stimulating living tissue(s) using a substantially continuous set of pulses wherein the stimulating includes (i) successively selecting a stimulation set from the plurality of stimulation sets in a cyclical manner; (ii) generating a pulse according to the pulse characteristic of the selected stimulation set; and (iii) delivering the generated pulse to living tissue(s) through electrodes according to the electrode configuration of the selected stimulation set;

wherein the stimulating generates and delivers each adjacent pulse within a single stimulation cycle through the plurality of stimulation sets using a fixed interval;

wherein the stimulating repeats the generating and delivering for the at least one of the plurality of stimulation sets to generate and deliver a number of pulses equal to the repetition parameter within the single stimulation cycle.

For the reasons discussed above in regard to claims 24 and 28, the applied references do not teach or suggest each and every limitation of claim 32. Additionally, Applicant notes that Reiss utilizes different pulse rates for the first and second periods. Accordingly, there is not a fixed interval between adjacent pulses at the transition between the first period and the second period. Specifically there is a change in pulse frequency or pulse rate at the transition between the first and second periods. Therefore, there is not a fixed interval between each adjacent pulse in Reiss.

Applicant respectfully submits that claim 32 is patentable over the applied references. Claims 33-35 depend from claim 32 and are likewise patentable over the applied references.

Conclusion

Applicant respectfully submits that the application is in condition for allowance and requests the Examiner to pass the application to issue. Applicant believes no fee is due with this response. However, if a fee is due, please charge Deposit Account No. 50-3906 from which the undersigned is authorized to draw.

Applicant does not believe that an extension of time is necessary, because this amendment and accompanying RCE has been filed within two months of the filing of a notice of appeal. However, if any extension of time is necessary, Applicant hereby petitions for such extension of time and authorizes the Office to charge Deposit Account No. 50-3906 from which the undersigned is authorized to draw for the appropriate extension of time fee.

Dated: 11-03-2006

Respectfully submitted,

By /Christopher S.L. Crawford/
Christopher S.L. Crawford, Reg. No. 51,586
Advanced Neuromodulation Systems, Inc.
6901 Preston Road
Plano, TX 75024
Telephone No: (972) 309-8006